Remarks

The Office action mailed February 17, 2004, has been received and reviewed. Claims 25-30, 55-60 and 85-90 were elected in a response to a restriction requirement. As such, claims 25-30, 55-60 and 85-90 are pending herein. Claim 91 has been added. Reconsideration of the application in view of the following remarks is respectfully requested.

35 U.S.C. § 103(a) Rejections

To establish a *prima facie* case of obviousness, three criteria must be met:

1) there must be some suggestion or motivation to modify the reference or to combine reference teachings;

2) there must be a reasonable expectation of success; and

3) the prior-art references must teach or suggest all the claim limitations.

Moreover, the teaching or suggestion, and the reasonable expectation of success must be found tin the prior art and not be based on applicants' disclosure. *See* MPEP § 706.02(j), § 2142, and § 2143.

Obviousness Rejection Based on the Ichikawa, Evans and Reinhoff References

Claims 25-26, 29-30, 55-56, 59-60, 85-87 and 89-90 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over the Ichikawa reference (Internal Medicine (July 200) Vol. 39, no. 7, pp. 523-524) in view of the Evans reference (Science (Oct. 1999) Vol. 286, pp 487-491) and the Reinhoff reference (US 2002/0049772 A1, filed 5/26/2000).

Applicants kindly submit that a *prima facie* case of obviousness has not been established with respect to independent claims 25, 55 and 85 and traverse the rejection. Furthermore, as claims 26, 29-30, 56, 59-60, 86-87 and 89-90 depend either directly or indirectly from an independent claim, Applicants maintain that a prima facie case of obviousness has not been established as to these claims as well.

1) Suggestion or Motivation

As mentioned in Applicants' previous response, the Ichikawa reference fails to teach or suggest, the computerized steps of accessing a list of risk-associated agents if a genetic test result value is a polymorphism value associated with an atypical event and outputting an interpretation of one or more genetic test result values and a list of risk-associated agents, as recited in independent claim 25. The Ichikawa reference fails to teach or suggest, a computer system for processing hereditary data related to the use of clinical agents by a person that includes an accessing component for accessing a list of risk-associated agents if the determining component determines that a genetic test result value is a polymorphism value associated with an atypical event and an outputting component for outputting component for outputting an interpretation of one or more genetic test result values and a list of risk-associated agents, as recited in independent claim 55. Also, the Ichikawa reference fails to teach or suggest instructions on a computer readable medium that includes accessing a list of risk-associated agents and outputting an interpretation of one or more genetic test result values and a list of risk-associated agents, as recited in independent claim 85.

Rather, the method of the Ichikawa reference teaches that a particular single nucleotide polymorphism can be used to disclose severe side effects or proper dosage for a patient. The Ichikawa reference lacks any teaching or suggestion of computerized steps of accessing a list of risk-associated agents and outputting an interpretation of one or more genetic test result values and a list of risk-associated agents in a computer system. The Ichikawa reference merely teaches a patient with an autosomal recessive trait for TMPT deficiency may show severe and potentially fatal leukopekia if treated with aqathioprine or mercaptopurine. There is no suggestion in the Ichikawa reference to automate accessing a list of risk-associated

agents if a genetic test result value is a polymorphism value associated with an atypical event and outputting interpretation of one or more genetic test result values and a list of risk-associated agents in a computerized system without user intervention.

Like Ichikawa, the Evans reference also fails to teach or suggest a method in a computer system the computerized steps of accessing a list of risk-associated agents if a genetic test result value is a polymorphism value associated with an atypical event and outputting an interpretation of one or more genetic test result values and a list of risk-associated agents as recited in independent claim 25. The Evans reference also fails to teach or suggest, a method in a computer system for processing hereditary data related to the use of clinical agents by a person that includes automated computer components such as an accessing component for accessing a list of risk-associated agents for a genetic test result value and an outputting component for outputting an interpretation of one or more genetic test result values and a list of risk-associated agents, as recited in independent claim 55. Also, the Evans reference fails to teach or suggest instructions on a computer readable medium that includes accessing a list of risk-associated agents and outputting an interpretation of one or more genetic test result values and a list of risk-associated agents, as recited in independent claim 85.

Rather, the Evans reference discloses translating functional genomics into rational therapeutics. The Evans reference provides examples of clinically relevant genetic polymorphisms influencing drug metabolism and effects. The Evans reference lacks any teaching or suggestion of computerized steps for accessing a list of risk-associated agents and outputting an interpretation of one or more genetic test result values and a list of risk-associated agents. The Evans reference merely chronicles the fact that automated systems are being developed to determine an individual's genotype for polymorphic genes. The discussion of

automated systems is limited to automated systems for determining an individual's genotype and does not discuss accessing and outputting a list of risk-associated agents for a particular genotype. There is no teaching or suggestion in Evans that an automated computer system may be used to associate an individual's genotype for a polymorphic gene with a list of risk-associated agents and outputting a list of risk-associated agents.

The Office Action states that "it would have been obvious to one of ordinary skill in the art at the time of invention to have computerized, or automated, the genetic screening method of Ichikawa, as taught by Reinhoff, and to have accessed a list of treatment/drug options, as taught by Evans, in the automated method of Ichikawa and Reinhoff, where the motivation would have been to use the method to identify patients appropriate for treatment when a choice is to be made among various options, as taught by Reinhoff."

Even if Reinhoff can be combined with Ichikawa and Evans, although Applicants do not concede that it can, the mere fact that references **can** be combined does not render the resultant combination obvious unless the prior art also **suggests** the desirability of the combination. *In re Kotzab*, 217 F.3d 1365, 1371, 55 USPQ2d 1313, 1318 (Fed. Cir. 1990) and MPEP §2134.01, emphasis added. Applicants submit that no suggestion nor motivation to modify Ichikawa and Evans or to combine Ichikawa and Evans with Reinhoff exists. Rather, the Reinhoff reference teaches a computer program product for separating individuals into subpopulations using a polymorphic profile in a networked environment. Reinhoff says that when a polymorphism is known to be associated with a response to treatment (such as an agent), this information may be used to allocate the most appropriate dose to subjects enrolled in a treatment study such as a clinical trial. (Paragraph 0057) The polymorphic profiles of individuals can determine the degree of response of individuals to the treatment (agent).

Furthermore, as cited by the Examiner, the profile can be used as a diagnostic to identify patients appropriate for treatment when the decision to treat or a choice of treatment is made. Applicants submit that one of skill in the art would not use the Reinhoff reference as a motivation to computerize or automate accessing a list of risk-associated agents and outputting the list of risk-associated agents because the treatment (agent) is already known. As the treatment (agent) to be used in clinical trials as discussed in the Reinhoff reference is already known, there is no need to access a list of risk-associated agents and output the list of risk-associated agents.

Applicants respectfully note that it is impermissible to use the claimed invention as an instruction manual or template to piece together the teaching of the prior art so that the claimed invention is rendered obvious. The Office Action cannot use hindsight to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention. *In re Fritch*, 972 F.2d 1260, 23 USPQ 2d 1780 (Fed. Cir. 1992). Applicants respectfully submit hindsight is employed to assert that claims 25, 55 and 85 are rendered obvious by Ichikawa in view of Evans and Reinhoff.

2) Reasonable Expectation of Success

There must be a reasonable expectation of success. The Office Action offers no reasons as to why one skilled in the art should reasonably expect to succeed in making applicants' claimed invention from combining Reinhoff with Ichikawa and Evans as there is no need to access and output a list of risk-associated agents in Reinhoff as the treatment (agent) is already known.

As a *prima facie* case of obviousness has not been made for independent claims 25, 55 and 85, Applicants request withdrawal of the 103(a) rejection of these claims. Further, as

claims 26, 29-30, 56, 59-60, 86-87 and 89-90 depend directly or indirectly from independent claims 25, 55 and 85, Applicants request withdrawal of the rejection of these claims as well.

Obviousness Rejection Based on the Ichikawa, Evans, Reinhoff and Fey References

Claims 28, 58 and 88 have been rejected under 35 U.S.C. 103(a) as being unpatentable over the Ichikawa reference in view of the Evans reference and the Reinhoff reference and in further view of Fey et al. (US Pub. 20020038227, filed 2/26/01). Applicants submit that a *prima facie* case of obviousness has not been established with respect to claims 28, 58 and 88.

1) Suggestion or Motivation

As discussed above, the Ichikawa and Evans references fail to teach or suggest all of the limitations of independent claims 25, 55 and 85. Dependent claims 28, 58 and 88 depend either directly or indirectly from independent claims 25, 55 and 85. As discussed in Applicant's previous response, the Fey reference also fails to teach or suggest all of the limitations of independent claims 25, 55 and 85.

The Fey reference also fails to teach or suggest a method in a computer system for processing hereditary data related to the use of clinical agents by a person that includes the computerized steps of accessing a list of risk-associated agents if a genetic test result value is a polymorphism value associated with an atypical event and outputting an interpretation of one or more genetic test result values and a list of risk-associated agents as recited in independent claim 25, an accessing component and outputting as recited by independent claim 55 and instructions for accessing a list of risk-associated agents and outputting the list of risk-associated agents as recited by independent claim 85.

Rather, the Fey reference discloses a method for centralized health data management. The Fey reference relates to a centralized health screening and management system. Data and test results are transmitted to a centralized data management system for analysis and storage in a manner that is accessible for report generation and aggregate information analysis. The Fey reference in no way suggests instructions computerized method steps for accessing a list of risk-associated agents and outputting an interpretation of one or more genetic test results values and a list of risk-associated agents as recited by independent claim 85. The Fey reference merely discusses storing health data in a manner that is accessible. The Fey reference does not suggest computerized steps for accessing a list of risk-associated agents for a genetic test result value that is a polymorphism value associated with an atypical event nor does it suggest outputting a list of risk-associated agents.

The Office Action states that "it would have been obvious to one of skill n the art at the time of invention to accessed the medical records in the method of Ichikawa, Evans and Reinhoff in a comprehensive healthcare system/database, as taught by Fey, where the motivation would have been to associate phenotypic information specific for a patient with genotypic information in a clinical setting in order to better treat/test the patient, as taught by Reinhoff (paragraph 67)."

Again, Reinhoff cannot be combined with Ichikawa and Evans as it does not suggest the desirability of the combination. *In re Kotzab*, 217 F.3d 1365, 1371, 55 USPQ2d 1313, 1318 (Fed. Cir. 1990) and MPEP §2134.01. Applicants submit that no suggestion nor motivation to modify Ichikawa and Evans or to combine Ichikawa and Evans with Reinhoff exists. Rather, the Reinhoff reference teaches that it is appropriate to exclude individuals in a clinical trial of a known therapy if it is known they will present a particular phenotype. Again,

the therapy (agent) used for the clinical trial is known. Applicants submit that one of skill in the art would not use the Reinhoff reference as a motivation to computerize or automate accessing a list of risk-associated agents and outputting the list of risk-associated agents because therapy (agent) is already known. As the therapy (agent) to be used in clinical trials as discussed in the Reinhoff reference is already known, there is no need to access a list of risk-associated agents and outputting the list of risk-associated agents.

As a *prima facie* case of obviousness has not been made for independent claims 25, 55 and 85, from which claims 28, 58 and 88 depend either directly or indirectly, Applicants request withdrawal of the 103(a) rejection of claims 28, 58 and 88.

New Claim 91

Additionally, new Claim 91 is patentable even if Reinhoff were properly combinable, though Applicants do not concede that it is. New claim 91 recites a method in a computer system for processing hereditary data related to the use of clinical agents by a person, comprising the steps of receiving a genetic test result value for the person; determining if the genetic test result value is a polymorphism value associated with an atypical clinical event, and if so, accessing a list of risk-associated agents; outputting an interpretation of the genetic test result value and the list of risk-associated agents; and determining if the person has been exposed to an agent on the list of risk-associated agents. The feature of determining if the person has been exposed to an agent on the list of risk-associate agents is neither taught nor suggested by Ichikawa, Evans, Fey or Reinhoff.

In light of the above arguments, Applicants submit that claims 25-30, 55-60, and 85-91 are in condition for allowance. As such, Applicant respectfully request that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

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